

**RECEIVED
U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

TO: Director of the U.S. Patent and Trademark Office P.O. Box 450 Alexandria, VA 22313-0450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
--	---

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the NORTHERN DISTRICT OF CALIFORNIA on the following:

Trademarks or Patents. (the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA
PLAINTIFF GENENTECH and ROCHE PALO ALTO, LLC	DEFENDANT APOTEX INC.	CV 11 2410
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 6,083,953	7/4/2000	Roche Palo Alto
2		
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK RICHARD W. WIEKING	(BY) DEPUTY CLERK JESSIE MOSLEY	DATE MAY 19 2011
------------------------------------	---	----------------------------

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

1 STEPHEN S. RABINOWITZ
2 srbabinowitz@friendfrank.com
3 RANDY C. EISENSMITH (*Pro Hac Vice Pending*)
4 randy.eisensmith@friedfrank.com
5 FRIED, FRANK, HARRIS, SHRIVER
6 & JACOBSON LLP
7 ONE NEW YORK PLAZA
8 NEW YORK, NEW YORK 10001
9 Telephone: 212-859-8000
10 Facsimile: 212-859-4000

11 DURIE TANGRI LLP
12 DARALYN J. DURIE (SBN 169825)
13 ddurie@durietangri.com
14 JOSHUA H. LERNER (SBN 220755)
15 jlerner@durietangri.com
16 GENEVIEVE P. ROSLOFF (SBN 258234)
17 grosloff@durietangri.com
18 217 Leidesdorff Street
19 San Francisco, CA 94111
20 Telephone: 415-362-6666
21 Facsimile: 415-236-6300

22 Attorneys for Plaintiffs
23 GENENTECH, INC. and
24 ROCHE PALO ALTO LLC

DMR

15 UNITED STATES DISTRICT COURT
16 FOR THE NORTHERN DISTRICT OF CALIFORNIA

17 CV 11 2410

18 GENENTECH, INC. and
19 ROCHE PALO ALTO LLC,

Case No.

20 COMPLAINT

21 Plaintiffs,

22 v.

23 APOTEX INC.

24 Defendant.

25
26
27
28
COMPLAINT

1 Plaintiffs Genentech, Inc. and Roche Palo Alto LLC, by their attorneys, for their Complaint in
2 this action allege:

3 **PARTIES**

4 1. Genentech, Inc. ("Genentech") is a corporation organized and existing under the laws of
5 the State of Delaware, having its principal place of business at 1 DNA Way, South San Francisco,
6 California 94080-4990.

7 2. Roche Palo Alto LLC ("Roche Palo Alto") is a limited liability company organized and
8 existing under the laws of the State of Delaware, having its principal place of business at 3431 Hillview
9 Avenue, Palo Alto, California 94304-1397.

10 3. On information and belief, Apotex Inc. ("Apotex") is a company organized and existing
11 under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada.

12 **JURISDICTION**

13 4. This action arises under the Patent Act of 1952, as amended, 35 U.S.C. §§ 1-376.

14 5. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331 and
15 1338(a).

16 **INTRADISTRICT ASSIGNMENT**

17 6. For purposes of intradistrict assignment pursuant to Civil Local Rules 3-2(c) and 3-5(b),
18 this Intellectual Property Action is to be assigned on a district-wide basis.

19 **THE PATENT IN SUIT**

20 7. On July 4, 2000, the United States Patent and Trademark Office issued U.S. Patent No.
21 6,083,953 (the "'953 patent"), entitled "2- (2-amino-1,6-dihydro-6-oxo-purin-9-yl) methoxy-1,3-
22 propanediol Derivative." Roche Palo Alto is the owner by assignment of all right, title and interest in the
23 '953 patent. A copy of the '953 patent is attached hereto as Exhibit A.

24 8. Genentech markets and sells an FDA-approved pharmaceutical product, called
25 VALCYTE®, in the form of tablets containing 450 mg of the active pharmaceutical ingredient,
26 valganciclovir hydrochloride in crystalline form. The '953 patent is listed in the FDA's publication of
approved drugs, Approved Drug Products with Therapeutic Equivalence Evaluations (known as the
"Orange Book"), as covering VALCYTE® 450 mg tablets and their use.

1 APOTEX'S ANDA AND NOTICE LETTER

2 9. By letter to Roche Palo Alto and certain of its affiliates dated April 6, 2011 (the "Notice
3 Letter"), Apotex gave notice under Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act ("FDCA")
4 that it had submitted Abbreviated New Drug Application ("ANDA") No. 202785 to the FDA, seeking the
5 FDA's approval to manufacture, use and sell valganciclovir hydrochloride 450 mg tablets prior to
6 expiration of the '953 patent.

7 10. In the Notice Letter, Apotex notified Roche Palo Alto that its ANDA contained a
8 "Paragraph IV Certification" that the claims of the '953 patent will not be infringed by the commercial
9 manufacture, use, offer for sale and sale of certain valganciclovir hydrochloride 450 mg tablets (the
10 "Apotex Generic Product"). The Apotex Notice Letter asserts that such commercialization will not
11 infringe the '953 patent because the Apotex Generic Product purportedly will comprise "amorphous,"
12 rather than crystalline, valganciclovir hydrochloride.

13 11. In truth and in fact, amorphous valganciclovir hydrochloride is hygroscopic and prone to
14 conversion to crystalline form during use by patients, e.g. upon exposure to ambient conditions of
15 temperature and humidity.

16 12. Apotex has provided Roche Palo Alto and its affiliates with confidential access to a
17 portion of its ANDA but has refused to provide physical samples of the Apotex Generic Product and
18 related materials for testing.

19 13. On information and belief, Apotex threatens to market and sell the Apotex Generic
20 Product in California and elsewhere in the United States and thereby to cause massive infringement of
21 the '953 patent in California, in this district, and elsewhere in the United States.

22 14. On information and belief, Apotex is not qualified to do business in any State of the
23 United States. On information and belief, Apotex is not subject to jurisdiction in any state court of
24 general jurisdiction in the United States. On information and belief, Apotex derives substantial revenue
25 from sales of pharmaceutical products in California, in this district, and elsewhere in the United States.

26 15. This complaint is being filed before the expiration of forty-five days from the date Roche
27 Palo Alto and its affiliates received the Apotex Notice Letter.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '953 PATENT

16. Each of the preceding paragraphs 1 to 15 is incorporated herein as if set forth in full.

17. Plaintiffs believe and expect that following receipt of relevant Apotex physical materials, investigation will confirm that the valganciclovir hydrochloride active ingredient in the proposed Apotex Generic Product will comprise or convert to crystalline valganciclovir hydrochloride at least during use by patients, e.g. upon exposure to ambient atmospheric humidity during storage in pill trays.

18. On information and belief, Apotex's commercial use, offer for sale, and sale of the proposed Apotex Generic Product would infringe the '953 patent at least under 35 U.S.C. §§ 271(b) and (c).

19. On information and belief, Apotex infringed the '953 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 202785.

SECOND CLAIM FOR RELIEF
DECLARATORY AND EQUITABLE RELIEF
AGAINST THREATENED PATENT INFRINGEMENT

20. Each of the preceding paragraphs 1 to 19 is incorporated herein as if set forth in full.

21. Apotex has proposed and threatens to market, sell, and actively induce use of the Apotex Generic Product throughout the United States including in California and this federal judicial district.

22. On information and belief, Apotex's proposed and threatened use, offer for sale, and sale of the Apotex Generic Product will infringe or actively induce or contribute to infringement of the '953 patent.

23. An actual controversy exists between Plaintiffs and Apotex concerning whether offer for sale, sale, or use of the Apotex Generic Product in the United States will infringe the '953 patent.

24. Offer for sale, sale or use of the Apotex Generic Product in the United States would cause injury to Plaintiffs for which there is no adequate remedy at law.

PRAYER FOR RELIEF

25
26
27
28
WHEREFORE Plaintiffs pray that the Court:

(i) declare, adjudge, and decree that Apotex has infringed the '953 patent by submitting ANDA No. 202785;

(ii) declare, adjudge, and decree that Apotex's commercial use, offer for sale and sale of the Apotex Generic Product will infringe the '953 patent;

(iii) issue an Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Apotex Generic Product be no earlier than the expiration date of the '953 patent, or any later expiration of exclusivity to which Roche Palo Alto is or becomes entitled;

(iv) issue a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 283, and 28 U.S.C. § 1331 restraining and enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in commercial activity that would directly or indirectly infringe the '953 patent; and

(v) award such other and further relief as the Court may deem just and proper.

Dated: May 17, 2011

STEPHEN S. RABINOWITZ
RANDY C. EISENSMITH
FRIED, FRANK, HARRIS, SHRIVER
& JACOBSON LLP

DARALYN J. DURIE
JOSHUA H. LERNER
GENEVIEVE P. ROSLOFF
DURIE TANGRILL, L.P.

By: JOSHUA LERNER
JOSHUA H. LERNER

Attorneys for Plaintiffs
GENENTECH INC. and
ROCHE PALO ALTO LLC